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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,135	12/07/2001	Neil Russell Foster	HILLS1100	8942
28213	7590	05/06/2005	EXAMINER	
DLA PIPER RUDNICK GRAY CARY US, LLP			OH, SIMON J	
4365 EXECUTIVE DRIVE			ART UNIT	
SUITE 1100			PAPER NUMBER	
SAN DIEGO, CA 92121-2133			1618	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/017,135

**Applicant(s)**

FOSTER ET AL.

**Examiner**

Simon J. Oh

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Papers Received*

Receipt is acknowledged of the applicant's response to the restriction requirement of 14 December 2004, received on 27 December 2004.

### *Election/Restrictions*

Claims 25 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 27 December 2004.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-24 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merrified *et al.* (PCT Publication No. WO 00/37169) in view of Manning *et al.* (U.S. Patent No. 5,770,559)

The Merrified *et al.* publication discloses a process and apparatus for the production of particles using a solvent/anti-solvent process in which the anti-solvent is preferably a supercritical fluid (See Abstract). Suitable anti-solvents include ethane and ethylene. The anti-solvent stream may further comprise a modifier, such as methanol and ethanol (See Page 5, Line 19 to Page 6, Line 4). The compressible anti-solvent may be introduced at pressures of 50 to 100 bar at a suitable temperature, which is likely to be in the range of  $1.01 T_C$  to  $4.0 T_C$  (See Page 6, Lines 5-12; and Page 12, Lines 19-25). The apparatus may include a means for collection of the particles, such as a collection chamber (See Page 16, Line 21-29). The particles may be a pharmaceutical material, with a small particle size, such as around 1 to 20 microns (See Page 18, Lines 7-9).

The Merrified *et al.* publication does not explicitly disclose the insulin as a pharmaceutical material.

The Manning *et al.* patent discloses a solvent/anti-solvent process for precipitation of particles (See Column 3, Lines 1-12). Insulin is listed as a pharmaceutical substance that is suitable for the disclosed method of preparation (See Column 5, Line 63; and Examples).

It would be obvious for one of ordinary skill in the art to combine the disclosures of the prior art in order to obtain the instantly claimed invention. While the Merrified *et al.* reference does make mention of the use of pharmaceutical material in the disclosed invention, this disclosure was made in very broad terms. The Manning *et al.* patent provides more specific

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guidance on what specific active substances a solvent/anti-solvent process is particularly suitable to utilize. As both prior art references deal with solvent/anti-solvent precipitation processes using a supercritical fluid, they are considered to be analogous art. Thus, one of ordinary skill in the art would be able to combine the disclosures of the prior art with a reasonable expectation of success. Thus, the instantly claimed invention is *prima facie* obvious.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1618

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

sjo